Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2168365	05/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Celina Family Practice, Pllc	2740 Virginia Pkwy Ste 100, Mckinney, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced survey of the laboratory was conducted 05/08/2024 through 05/09 /2024. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: 42 C.F.R. 493.1250 Condition: Analytic systems 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer instructions for use, laboratory's policies /procedures, test verification studies, quality control records, calibration records, maintenance records, patient test records and staff interview, the laboratory failed to ensure overall quality of the analytic systems was maintained for 3 of 3 test platforms used by the laboratory, the Beckman Coulter DxH 500, Access 2 UniCel DxI and DxC AU480. Findings included: 1. Laboratory failed to include in its procedure manual 7 of 14 procedural requirements for its chemistry and hematology testing platforms. Refer to D5403. 2. Laboratory failed to follow manufacturer instructions for testing PSA on patients aged 50 years or older. Refer to D5411. 3. Laboratory failed to ensure verification studies were complete for 3 of 3 test platforms used by the laboratory. Refer to D5421. 4. Laboratory failed to follow manufacturer

	instructions for documentation of calibration of the Apolipoprotein B test every 7 days. Refer to D5437. 5. Laboratory's quality assurance failed to evaluate QC over time to detect shift and trends. Refer to D5791.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on Surveyor's observations, review of laboratory's policies/procedures and staff interview, the laboratory failed to include in its procedure manual 7 of 14 procedural requirements for its chemistry and hematology testing platforms, the Beckman Coulter DxH 500, Access 2 UniCel DxI and DxC AU480. Findings included: 1. Surveyor's observations on 05/08/2024 at 0905 hours in the laboratory revealed the laboratory used the following instruments for its chemistry and hematology testing: Beckman Coulter DxH 500 hematology analyzer, serial number (SN) BG050132 Beckman Coulter Access 2 UniCel DxI chemistry analyzer, SN 574622 Beckman Coulter DxC AU480 chemistry analyzer, SN 0070733 2. Review of laboratory's policies/procedures for its chemistry and hematology testing revealed the following 7 requirements of the procedure manual were not addressed for the above instruments and their tests: a. Control procedures (number of controls, frequency and acceptability criteria, corrective actions). b. Step-by-step performance of the procedure, including test calculations and interpretation of results. c. Calibration and calibration verification procedures (number of calibrators per test/analyte, frequency and acceptability criteria). d. Reference intervals (normal values). e. Reportable range, and actions for values outside that range. f. Addressing alert values, instrument flags or messages. g. Laboratory's system for entering results in the patient record and reporting patient results. 3. In an interview on 05/09/2024 at 1050 hours in the conference room, the Laboratory Manager (as indicated on submitted Survey Entrance /Exit Conference document) confirmed the findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

	following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use for the Beckman Coulter Access Hybritech PSA (Prostate Specific Antigen) test, laboratory's policies /procedures, random patient test records and staff interview, the laboratory failed to follow manufacturer instructions for testing PSA on patients aged 50 years or older for 5 of 20 patient records reviewed from January to May 2024. Findings included: 1. Review of manufacturer's instructions for use for the Beckman Coulter Access Hybritech PSA test (document A85067 R August 2023) revealed: "INTENDED USE ... This device is indicated for the measurement of serum PSA in conjunction with digital rectal examination (DRE) as an aid in detection of prostate cancer in men aged 50 years or older." 2. Review of laboratory's policy/procedure "PSA" (last reviewed 05 /07/2024) revealed the laboratory did not address age limitations for patient sample collection. 3. Review of laboratory's random patient test records from January to May 2024 revealed the following 5 patients tested for PSA were aged less than 50 years: Patient: MCKHF370310120 Date of birth: 08/31/1982 Age: 41 Tested: 02/09/2024 PSA result: 1.75 ng/mL Patient: 35316 Date of birth: 08/12/1975 Age: 48 Tested: 05 /01/2024 PSA result: 0.53 ng/mL (nanograms per milliliter) Patient: HF474462636 Date of birth: 06/12/1979 Age: 44 Tested: 05/03/2024 PSA result: 0.40 ng/mL Patient: HF268053386 Date of birth: 10/07/1980 Age: 43 Tested: 05/07/2024 PSA result: 0.54 ng/mL Patient: 35000 Date of birth: 05/09/1981 Age: 43 Tested: 05/07 /2024 PSA result: 0.48 ng/mL 4. In an interview on 05/08/2024 at 1430 hours in the conference room, the Laboratory Manager (as indicated on submitted Survey Entrance /Exit Conference document) confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's test verification studies and staff interview, the laboratory failed to ensure verification studies were complete for 3 of 3 test platforms used by the laboratory, Beckman Coulter DxH 500, Access 2 UniCel DxI and DxC AU480. Findings included: 1. Surveyor's observations on 05/08 /2024 at 0905 hours in the laboratory revealed the laboratory used the following instruments for its chemistry and hematology testing: Beckman Coulter DxH 500 hematology analyzer, serial number (SN) BG050132 Beckman Coulter Access 2 UniCel DxI chemistry analyzer, SN 574622 Beckman Coulter DxC AU480 chemistry analyzer, SN 0070733 2. Review of laboratory's verification studies for the above instruments revealed evaluation of the following parameters was not documented: a. Verification of the Beckman Coulter DxH 500 (completed in September 2023) did not

	have documentation of verification normal range. b. Verification of the Beckman Coulter Access 2 UniCel DxI (completed in October 2023) did not have documentation of verification of normal range. c. Verification of the Beckman Coulter DxC AU480 (completed in November 2023) did not have documentation of verification of normal range. 3. In an interview on 05/09/2024 at 1000 hours in the conference room, the Laboratory Manager (as indicated on submitted Survey Entrance /Exit Conference document) confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory's Beckman Coulter DxC AU480 instrument's maintenance requirements, instrument maintenance records and staff interview, the laboratory failed to document required maintenance for 17 of 17 instances maintenance was required from December 2023 through April 2024. Findings included: 1. Review of laboratory's Beckman Coulter DxC AU480 instrument's maintenance records revealed the following required instrument maintenance: Daily Weekly Every Other Week or 3,000 Samples (ISE Option) Monthly Monthly, Every Two Months, or Every Three Months (ISE Option) Every Other Month or Every 20,000 Samples Quarterly Quarterly or Every 20,000 Samples Every 6 months Annually As Needed Refer to master list for maintenance components of each timeframe above. 2. Further review of the of laboratory's Beckman Coulter DxC AU480 instrument's maintenance records from December 2023 through April 2024 revealed the following maintenance was not documented: Weekly maintenance not documented: Week of February 6, 2024 Week of February 13, 2024 Week of February 20, 2024 Week of February 27, 2024 Week of April 23, 2024 Week of April 30, 2024 Every Other Week or 3,000 Samples (ISE Option) maintenance not documented: Week of December 4, 2023 Week of December 18, 2023 Week of January 16, 2024 Week of March 4, 2024 Week of April 2, 2024 Week of April 16, 2024 Monthly maintenance not documented: December 2023 February 2024 March 2024 April 2024 Quarterly maintenance not documented: From December 2023 through April 2024. 3. In an interview on 05/08/2024 at 1545 hours in the conference room, the Laboratory Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration

	verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use for the Beckman Coulter AU /DxC AU Apolipoprotein B test, laboratory's calibration records, random patient test records and staff interview, the laboratory failed to follow manufacturer instructions for documentation of calibration of the Apolipoprotein B test every 7 days for 15 of 15 instances calibration was due in 22 weeks reviewed from December 2023 through April 2024. Findings included: 1. Review of the manufacturer's instructions for use for the "Beckman Coulter AU/DxC AU APO B Apolipoprotein B" test (document BAOSR6X43 08, December 2023) revealed: "The frequency of the calibration for the Apolipoprotein B procedure is every 7 days." 2. Review of laboratory's calibration records for the Beckman Coulter AU/DxC AU Apolipoprotein B test from December 2023 through April 2024 revealed the following days calibration was due but was not documented: Calibration Due: 12/13/2023 12/29/2023 01/05/2024 01/12/2024 02/16 /2024 02/23/2024 03/01/2024 03/08/2024 03/15/2024 03/22/2024 03/29/2024 04/05 /2024 04/12/2024 04/19/2024 04/26/2024 Note: The last time Apolipoprotein B Calibration was documented was on 02/09/2024. 3. Review of random patient test records for the interval 02/16/2024 to 03/30/2024 revealed the following patients were tested without 7 day Apolipoprotein B calibration documentation: Patient ID: Tested: HF460556639 02/16/2024 HF46409709 02/16/2024 HF460556639 02/16/2024 HF464609709 02/16/2024 HF269674239 02/16/2024 HF464460748 02/16/2024 HF464199207 02/16/2024 HF387826599 02/16/2024 HF464466246 02/16/2024 HF397972050 02/19/2024 HF464371198 02/20/2024 HF464901263 02/20/2024 14682 02/21/2024 HF392495973 02/21/2024 HF465097911 02/21/2024 HF466317336 02/27/2024 HF465590976 02/27/2024 17130 03/14/2024 HF418940150 03/27/2024 HF469747566 03/27/2024 4. In an interview on 05/09 /2024 at 1000 hours in the laboratory, Testing Person number 1 (as indicated on submitted Form CMS 209) confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: A. Based on surveyor's observations, review of manufacturer instructions, laboratory's temperature records, corrective action records and staff interview, the laboratory failed to document corrective action for out-of-range laboratory reagents/supplies' storage temperature for 53 of 53 instances storage temperature was out of manufacturer required range in 90 days reviewed from January to April 2024. Findings included: 1. Surveyor's observations on 05/09/2024 at 1050 hours in the laboratory's storage room revealed the following items stored on the shelves in the laboratory's storage room: BD Vacutainer K2 EDTA Blood Collection Tubes Lot: 4011521 Expiration date: 2025-05-31 Quantity: 400 (4 boxes of 100 tubes each) BD Vacutainer Serum Blood Collection Tubes Lot: 4059153 Expiration date: 2026-02-28 Quantity: 100 (1 box of 100 tubes) BD Vacutainer SST Blood Collection Tubes Lot: 4025422 Expiration date: 2025-01-31 Quantity: 500 (5 boxes of 100 tubes each) Beckman Coulter Wash Solution Lot: M311507 Expiration date: 2027-09-30

Quantity: 5 bottles Beckman Coulter ISE Buffer Solution Lot: M401488 Expiration date: 2025-05-31 Quantity: 9 bottles 2. Surveyor's observations on 05/09/2024 at 1050 hours in the laboratory's storage room revealed the following items stored on the shelves in the laboratory's refrigerator: Beckman Coulter ACCESS hFSH Lot: 338969 Expiration date: 2025-10-31 Quantity: 2 boxes Beckman Coulter ACCESS 25(OH) Vitamin D Total Lot: 339084 Expiration date: 2024-09-30 Quantity: 2 boxes Beckman Coulter ACCESS Testosterone Lot: 439236 Expiration date: 2025-01-31 Quantity: 4 boxes Beckman Coulter ACCESS Cortisol Lot: 339129 Expiration date: 2025-08-31 Quantity: 1 box Beckman Coulter ACCESS TPO Antibody Calibrators Lot: 389816 Expiration date: 2024-05-28 Quantity: 1 box Beckman Coulter ACCESS 25(OH) Vitamin D Total Calibrators Lot: 338731 Expiration date: 2024-05-31 Quantity: 1 box Beckman Coulter ACCESS hLH Calibrators Lot: 234084 Expiration date: 2024-05-31 Quantity: 1 box Beckman Coulter ACCESS Cortisol Calibrators Lot: 339005 Expiration date: 2024-11-30 Quantity: 1 box Beckman Coulter ACCESS Vitamin B12 Calibrators Lot: 234130 Expiration date: 2024-07-31 Quantity: 1 box Beckman Coulter ACCESS DHEA-S Calibrators Lot: 338396 Expiration date: 2024-06-30 Quantity: 1 box Beckman Coulter ACCESS DHEA-S Calibrators Lot: 339029 Expiration date: 2025-01-31 Quantity: 1 box Beckman Coulter Cholesterol Lot: 2625 Expiration date: 2025-06-01 Quantity: 1 box Beckman Coulter HDL-Cholesterol Lot: 2501 Expiration date: 2025-04-01 Quantity: 1 box Beckman Coulter Total Protein Lot: 2618 Expiration date: 2025-02-01 Quantity: 1 box Beckman Coulter ALP Lot: 2607 Expiration date: 2025-04-01 Quantity: 1 box Beckman Coulter Triglyceride Lot: 2623 Expiration date: 2025-04-01 Quantity: 1 box Beckman Coulter Total APO A1 Lot: 2564 Expiration date: 2025-08-01 Quantity: 1 box Beckman Coulter Amylase Lot: 2609 Expiration date: 2025-04-01 Quantity: 1 box Beckman Coulter Lactate Dehydrogenase Lot: 2584 Expiration date: 2025-04-01 Quantity: 1 box Beckman Coulter Direct Bilirubin Lot: 2622 Expiration date: 2024-12-01 Quantity: 1 box Beckman Coulter Creatinine Lot: 2714 Expiration date: 2026-01-01 Quantity: 1 box 3. Review of manufacturer instructions for storage of the above items revealed the following temperature requirements: BD Vacutainer K2 EDTA Blood Collection Tubes Storage temperature: 4-25C (Degrees Celsius) BD Vacutainer Serum Blood Collection Tubes Storage temperature: 4-25C BD Vacutainer SST Blood Collection Tubes Storage temperature: 4-25C Beckman Coulter Wash Solution Storage temperature: 2-25C Beckman Coulter ISE Buffer Solution Storage temperature: 2-25C Beckman Coulter ACCESS hFSH Storage temperature: 2-10C Beckman Coulter ACCESS 25(OH) Vitamin D Total Storage temperature: 2-10C Beckman Coulter ACCESS Testosterone Storage temperature: 2-10C Beckman Coulter ACCESS Cortisol Storage temperature: 2-10C Beckman Coulter ACCESS TPO Antibody Calibrators Storage temperature: 2-8C Beckman Coulter ACCESS 25(OH) Vitamin D Total Calibrators Storage temperature: 2-8C Beckman Coulter ACCESS hLH Calibrators Storage temperature: 2-8C Beckman Coulter ACCESS Cortisol Calibrators Storage temperature: 2-8C Beckman Coulter ACCESS Vitamin B12 Calibrators Storage temperature: 2-8C Beckman Coulter ACCESS DHEA-S Calibrators Storage temperature: 2-8C Beckman Coulter Cholesterol Storage temperature: 2-8C Beckman Coulter HDL-Cholesterol Storage temperature: 2-8C Beckman Coulter Total Protein Storage temperature: 2-8C Beckman Coulter ALP Storage temperature: 2-8C Beckman Coulter Triglyceride Storage temperature: 2-8C Beckman Coulter Total APO A1 Storage temperature: 2-8C Beckman Coulter Amylase Storage temperature: 2-8C Beckman Coulter Lactate Dehydrogenase Storage temperature: 2-8C Beckman Coulter Direct Bilirubin Storage temperature: 2-8C Beckman Coulter Creatinine Storage temperature: 2-8C 4. Review of laboratory's temperature records revealed: a. Storage room temperature acceptable range was defined as "(18-25 C) 64.4 -77F (Degrees Fahrenheit)." b. Refrigerator temperature

	acceptable range was defined as "(2-8C) 35.6-46.4F." 5. Further review of the temperature records from January to April 2024 revealed following days storage temperature was out of manufacturer required range: a. Out of 64.4 -77F range Storage Room temperature Date: Temperature (F): 01/22/2024 78 01/23/2024 78 01 /24/2024 78 01/25/2024 78 01/26/2024 79 01/29/2024 79 01/30/2024 79 01/31/2024 79 02/01/2024 78 02/02/2024 78 02/05/2024 79 02/06/2024 79 02/07/2024 79 02/08 /2024 78 02/09/2024 78 02/12/2024 79 02/13/2024 79 02/14/2024 79 02/15/2024 79 02/16/2024 79 02/19/2024 79 02/20/2024 78 02/21/2024 78 02/22/2024 79 02/23 /2024 79 02/26/2024 79 02/27/2024 79 02/28/2024 78 02/29/2024 79 b. Out of 35.6-46.4F range Refrigerator temperature Date: Temperature (F): 01/15/2024 30.7 01/17 /2024 33 01/18/2024 33.3 01/19/2024 34 01/22/2024 34.2 01/23/2024 34 01/24/2024 35.3 02/07/2024 35.4 02/12/2024 32 02/13/2024 33.6 02/14/2024 34.2 02/15/2024 35 03/06/2024 35.1 03/07/2024 34.9 03/08/2024 34.6 03/12/2024 35.1 03/13/2024 35 03 /15/2024 35.2 03/18/2024 35 03/26/2024 35.4 03/28/2024 35 04/03/2024 35.2 04/22 /2024 35 04/23/2024 35.2 6. Review of laboratory's corrective action records revealed there was no documentation of corrective action for any of the 53 instances laboratory reagents/supplies' storage temperature was out of manufacturer required range. 7. In an interview on 05/09/2024 at 1050 hours in the conference room, the Laboratory Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings. B. Based on review of laboratory's humidity records, corrective action records and staff interview, the laboratory failed to ensure corrective action was documented for out-of-range humidity for 62 of 83 days reviewed from December 2023 to March 2024. Findings included: 1. Review of laboratory's humidity records revealed the laboratory defined acceptable limits for humidity as "30-70 % (percent)". 2. Review of laboratory's humidity records from December 2023 to March 2024 revealed the following days humidity was out of laboratory's defined range: Date: Humidity (%): 12/01/2023 12 12/04/2023 11 12/05/2023 12 12/06/2023 15 12 /07/2023 14 12/08/2023 15 12/11/2023 16 12/12/2023 15 12/13/2023 14 12/14/2023 16 12/15/2023 14 12/18/2023 13 12/19/2023 13 12/20/2023 15 12/21/2023 14 12/22 /2023 15 12/27/2023 17 12/28/2023 17 12/29/2023 15 01/02/2024 22 01/03/2024 22 01/04/2024 21 01/05/2024 20 01/08/2024 19 01/09/2024 17 01/10/2024 17 01/11 /2024 16 01/12/2024 16 01/15/2024 13 01/16/2024 11 01/17/2024 13 01/18/2024 13 01/19/2024 14 01/22/2024 16 01/23/2024 16 01/24/2024 18 01/25/2024 18 01/26 /2024 20 01/29/2024 20 01/30/2024 20 01/31/2024 20 02/01/2024 23 02/02/2024 23 02/05/2024 21 02/06/2024 25 02/07/2024 26 02/08/2024 25 02/09/2024 25 02/12 /2024 27 02/13/2024 27 02/14/2024 27 02/15/2024 26 02/16/2024 26 02/19/2024 25 02/20/2024 25 02/21/2024 24 02/22/2024 23 02/23/2024 23 02/26/2024 19 02/27 /2024 20 02/28/2024 23 02/29/2024 20 3. Review of laboratory's corrective action records revealed the laboratory did not have documentation of corrective action for the above 62 instances humidity was out of laboratory defined range. 4. In an interview on 05/09/2024 at 1050 hours in the conference room, the Laboratory Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, quality control (QC) records, and staff interview, the laboratory's quality assurance failed to have protocols in place for evaluation of QC over time to detect shift and trends for 3 of 3 test platforms used by the laboratory, Beckman Coulter DxH 500, Access 2 UniCel DxI and DxC AU480. Findings included: 1. Review of laboratory's policies/procedures revealed there were no quality assessment protocols in place addressing over time QC (Levey-Jennings charts) evaluation for errors, shifts or trends. 2. Review of laboratory's QC records from December 2023 through April 2024 revealed the laboratory printed monthly Levey-Jennings charts (QC data plots) for the following instruments: Beckman Coulter DxH 500 Beckman Coulter Access 2 UniCel DxI Beckman Coulter DxC AU480 3. Further review of the QC data for the above instruments revealed there was no documentation of evaluation over time of the Levey-Jennings charts for errors, shifts and trends. 4. In an interview on 05/08/2024 at 1500 hours in the conference room, the Laboratory Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions for use, laboratory's verification test studies, quality control (QC) records, calibration records, maintenance records, quality assurance, policies/procedures, personnel records and staff interview, the laboratory director failed to ensure overall management and direction was provided for 3 of 3 test platforms used by the laboratory, Beckman Coulter DxH 500, Access 2 UniCel DxI and DxC AU480. Findings included: 1. Laboratory director failed to ensure laboratory provided quality laboratory services for all requirements of test performance for 3 of 3 test platforms used by the laboratory. Refer to D6007. 2. Laboratory director failed to ensure verification studies were complete for 3 of 3 test platforms used by the laboratory. Refer to D6013. 3. Laboratory director failed to ensure 1 of 1 testing personnel had documentation of appropriate training to perform testing on the Beckman Coulter DxH 500 hematology analyzer. Refer to D6029.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by:

	Based on review of manufacturer's instructions for use, laboratory's quality control (QC) records, calibration records, maintenance records, quality assurance, policies /procedures and staff interview, the laboratory director failed to ensure laboratory provided quality laboratory services for all aspects of test performance for 3 of 3 test platforms used by the laboratory, Beckman Coulter DxH 500, Access 2 UniCel DxI and DxC AU480. Refer to D5411, D5429, D5437, D5785, D5791.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's test verification studies and staff interview, the laboratory director failed to ensure verification studies were complete for 3 of 3 test platforms used by the laboratory, Beckman Coulter DxH 500, Access 2 UniCel DxI and DxC AU480. Refer to D5421.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory's submitted form CMS 209 Laboratory personnel Report (CLIA), policies/procedures, personnel records, patient test records and staff interview, the laboratory director failed to ensure 1 of 1 testing personnel had documentation of training to perform testing on the Beckman Coulter DxH 500 hematology analyzer prior to testing patients' specimens. Findings included: 1. Review of laboratory's submitted form CMS 209 revealed the laboratory employed one testing person (TP1). 2. Review of laboratory's policy/procedure "Quality Assurance Plan"(approved 05/07/2024) revealed: "All personnel involved in any function affecting data quality will have sufficient training and technical expertise to effectively execute their job requirements." 3. Review of laboratory's personnel records revealed TP1 qualified for moderate complexity testing with High School Diploma equivalency but did not have documentation of training for the Beckman Coulter DxH 500 hematology analyzer. 4. Review of laboratory's patient test records revealed TP1 started testing patient samples on the Beckman Coulter DxH

	hematology analyzer in December 2023. 5. Review of random patient test reports from December 2023, and January and March 2024 revealed the following patients were tested by TP1 on the DxH 500 instrument: Patient Identification: Tested: HF458300617 12/18/2023 MCKHF372440233 12/19/2023 HF404825589 12/22/2023 HF445953635 01/03/2024 HF459880116 01/03/2024 HF445032458 01/19/2024 MCKHF443219439 03/27/2024 HF418940150 03/27/2024 HF427178983 03/27/2024 HF469864776 03/27/2024 6. In an interview on 05/09/2024 at 0910 hours in the conference room, the Laboratory Manager (as indicated on submitted Survey Entrance /Exit Conference document) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid